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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,934	10/27/2003	Jacob Richter	2388/46607	2137

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EXAMINER	
TYSON, MELANIE RUANO	
ART UNIT.	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,934	RICHTER ET AL.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 28 December 2006. All corrections made are accepted.

Response to Arguments

1. Applicant's arguments with respect to claims 32-43 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritch et al. (Patent No. 5,092,837).

Ritch et al. disclose a method comprising the steps of providing an intraocular implant (Figure 4D; tube 21, an outlet end having a flange 24, an inlet end located opposite the outlet end, and tube passage 36), providing a delivery device (16, Figure 4A; comprising a rod-like instrument 34, handles 38, 31, and 32, a tip 35, and an abutment surface, which is the outside surface of tip 35), attaching the implant (21) to the delivery device (16) with the tip (35) of the rod-like instrument (34) penetrating the tube passage (36) of the implant (column 5, lines 60-63) and the abutment surface (outside surface of tip 35) abutting the flange (since it touches flange 24 along the inside border; see Figure 4B), directing the implant (21) by the delivery device (16) to the

implantation site (column 4, line 57), inserting the implant (21) through the sclera (18) at the implantation site (column 6, lines 6-31) such that the inlet end is located within the anterior chamber of the wall (see Figure 4D), and withdrawing the delivery device (column 6, lines 37-40). Figures 4A-4B show the abutment surface (outside surface of tip 35) of the delivery device (16) has an angle generally corresponding to an angle of the flange (24) of the intraocular implant.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ritch et al. in view of Donowitz et al. (3,788,327).

Ritch et al. disclose a method comprising the steps of providing an intraocular implant (Figure 4D; tube 21, an outlet end having a flange 24, an inlet end located opposite the outlet end, and tube passage 36), providing a delivery device (16, Figure

4A; comprising a rod-like instrument 34, handles 38, 31, and 32, a tip 35, and an abutment surface, which is the outside surface of tip 35), attaching the implant (21) to the delivery device (16), directing the implant (21) by the delivery device (16) to the implantation site (column 4, line 57), inserting the implant (21) through the sclera (18) at the implantation site (column 6, lines 6-31) such that the inlet end is located within the anterior chamber of the wall (see Figure 4D), and withdrawing the delivery device (column 6, lines 37-40). Ritch et al. does not disclose the tube (21) has a pointed tip at the inlet end of the tube (21).

Donowitz et al. disclose a method comprising the step of providing an intraocular implant (Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Donowitz et al. teach providing the inlet end (38) with a pointed tip (36). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a pointed tip on the inlet end of the implant of Ritch et al. instead of a second flange as taught by Donowitz et al. in order to provide a device that is simple in construction, thus reduces manufacturing costs, yet still remains effective in controlling excessive intraocular pressure (column 1, lines 46-50).

7. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. in view of Rubinstein (Patent No. 5,433,701), and further in view of Prywes (Patent No. 6,007,511).

Donowitz et al. disclose a method comprising the step of providing an intraocular implant (Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Although Donowitz et al. disclose

directing the implant to the implantation site, whether it is directly through the cornea or through other areas of the eye (column 4, lines 14-17), Donowitz et al. do not specifically disclose inserting the implant through scleral tissue.

Rubinstein discloses a method comprising the steps providing an intraocular implant (Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22), and teaches inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and teaches the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), in order to minimize the possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the intraocular implant through scleral tissue as taught by Rubinstein in order to further facilitate the removal of aqueous from the anterior chamber of the eye, thus reducing intraocular pressure (column 1, lines 54-57 and column 2, lines 30-31). Donowitz et al. in view of Rubinstein do not disclose attaching the implant to a delivery device and directing the implant to the implantation site by the delivery device.

Prywes discloses an implant for the treatment of glaucoma (Figures 17-20, element 10). Prywes teaches a method comprising the steps of attaching the implant (10) to a delivery device (20), directing the implant (10) by the delivery device (20) to the

implantation site, inserting the implant (10), and withdrawing the device (column 10, lines 31-45; Figures 17-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Prywes in order to be able to carry out the procedure in a single stage, resulting in a faster procedure with minimal trauma to the eye (column 2, lines 50-56 and 23-26).

8. Claims 37-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donowitz et al. in view of Rubinstein in view of Prywes as applied to the claims above, and further in view of Wong et al. (Patent No. 5,000,731).

Donowitz et al. disclose a method comprising the step of providing an intraocular implant (Figure 4; tube 28, an inlet end 38, an outlet end opposite the inlet end having a flange 34, and tube passage 30). Although Donowitz et al. disclose directing the implant to the implantation site, whether it is directly through the cornea or through other areas of the eye (column 4, lines 14-17), Donowitz et al. do not specifically disclose inserting the implant through scleral tissue.

Rubinstein discloses a method comprising the steps providing an intraocular implant (Figure 2, element 10; having an inlet end 12 with a beveled surface 16, an outlet end 14, and passages 28 and 22), and teaches inserting the intraocular implant (Figure 2, element 10) through scleral tissue at the implantation site such that the inlet end (12) of the implant (10) is located within the anterior chamber of the eyeball (column 7, lines 18-23; Figure 2) and teaches the beveled surface (16) at the inlet end (24) of the implant (10) faces away from the iris (Figure 2, element 21), in order to minimize the

possibility that the iris (21) will obstruct the passage of aqueous humor from the anterior chamber of the eye into the tube passageway (22) of the implant (column 3, lines 48-68, through column 4, lines 1-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the intraocular implant through scleral tissue as taught by Rubinstein in order to further facilitate the removal of aqueous from the anterior chamber of the eye, thus reducing intraocular pressure (column 1, lines 54-57 and column 2, lines 30-31). Donowitz et al. in view of Rubinstein do not disclose attaching the implant to a delivery device and directing the implant to the implantation site by the delivery device.

Prywes discloses an implant for the treatment of glaucoma (Figures 17-20, element 10). Prywes teaches a method comprising the steps of attaching the implant (10) to a delivery device (20), directing the implant (10) by the delivery device (20) to the implantation site, inserting the implant (10), and withdrawing the device (column 10, lines 31-45; Figures 17-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the implant of Donowitz et al. in view of Rubinstein to a delivery device as taught by Prywes in order to be able to carry out the procedure in a single stage, resulting in a faster procedure with minimal trauma to the eye (column 2, lines 50-56 and 23-26). Donowitz et al. in view of Rubinstein in view of Prywes do not disclose a visible marker comprising a circumferential hole on the implant.

Wong et al. disclose an implant (Figure 1, not labeled) providing a passage for fluid flow in order to reduce pressure within an organ. Wong et al. teach circumferential

holes (13) in order to facilitate fluid drainage (column 3, lines 43-47). It is obvious that these circumferential holes (13) may be used as "markers" since they are located on the inlet end of the tube, which would be clearly visible on the implant upon penetration through the scleral tissue (see Figure 1 of Donowitz et al. for illustration). Therefore, to construct the implant of Donowitz et al. in view of Rubinstein in view of Prywes with markers, such as circumferential holes, as taught by Wong et al. would have been obvious to one of ordinary skill in the art at the time the invention was made in order to further facilitate aqueous humor drainage.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MT
February 2, 2007

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SUPERVISORY PATENT EXAMINER
2/5/07